

June 15, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Jagasthesan Moodley  
(U.S. National Stage Application  
based on Intl. Application No. PCT/IB04/003414, Filed July 30, 2004)  
U.S. Application No. 10/566,458  
Filed January 30, 2006

Title PROCESS AND MACHINE FOR  
AUTOMATED MANUFACTURE  
OF GASTRO-RETENTIVE DEVICES

Attorney Docket No. 26,591 B USA

Office of Initial Patent Examination's  
Filing Receipt Corrections  
P.O. Box 1450  
Alexandria, VA 22313-1450

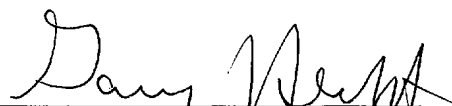
**REQUEST FOR CORRECTED FILING RECEIPT**

Sir:

Enclosed is a marked-up copy of the Official Filing Receipt issued by the United States Patent and Trademark Office for the above-captioned application on May 30, 2006 showing an error in the "Title" portion of the Filing Receipt. The correct Title of the application is "PROCESS AND MACHINE FOR AUTOMATED MANUFACTURE OF GASTRO-RETENTIVE DEVICES", as evidenced by the enclosed copies of (1) page 1 of the Application Data Sheet; and (2) page 1 of the Specification, both of which were submitted with the application on January 30, 2006.

Since this Request was necessitated because of an error made by the Patent Office, applicant believes no fee is due.

Respectfully submitted,

  
Gary A. Hecht, Reg. No. 36,826  
Attorney for Applicant

SYNNESTVEDT & LECHNER LLP  
Suite 2600 Aramark Tower  
1101 Market Street  
Philadelphia, PA 19107  
(215) 923 4466 - Telephone  
(215) 923-2189 - Facsimile  
MSimpson@synnlech.com - Email

S:\M\MERRION\Patents\P26591-B USA\PTO\Request for Corr.Fil Rec...doc

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
DESIGNATED/ELECTED OFFICE**

**Applicant: Jagathesan Moodley**

**GAU: Unknown**

**Application No.: Unknown**

**Examiner: Unknown**

**Filed: Herewith**

**Atty. Docket No. P26,591-B USA**

**For: PROCESS AND MACHINE FOR  
AUTOMATED MANUFACTURE OF  
GASTRO-RETENTIVE DEVICES**

**Express Mail Label No.  
EV 770775846 US**

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION DATA SHEET  
37 C.F.R. § 1.76**

**Application Information**

Application Type::	Regular
Subject Matter::	Utility
CD-ROM or CD-R?::	None
Title::	Process and Machine for Automated Manufacture of Gastro-Retentive Devices
Attorney Docket Number::	P26,591-B USA
Request for Early Publication?::	No
Request for Non-Publication?::	No
Suggested Drawing Figure::	3
Total Drawing Sheets::	24
Small Entity::	Yes
Petition included?::	No
Secrecy Order in Parent Appl.?::	No

PROCESS AND MACHINE FOR AUTOMATED  
MANUFACTURE OF GASTRO-RETENTIVE DEVICES

**Cross Reference To Related Application**

This application claims the priority of U.S. Provisional Application Number 60/491,157 filed July 30, 2003, which is hereby incorporated herein by reference.

**Background**

The present invention relates to a process and an apparatus for the automated manufacture of a gastro-retentive device. An example of such a device is a retard form of the type disclosed in U.S. Patent No. 4,996,058, which is hereby incorporated herein by reference, although the present invention is not limited to such retard forms, but is applicable to any gastro-retentive device.

The term "retard form," denotes a dosage form which effects delayed release of at least a portion of the active ingredient in the stomach and to the upper part of the small intestine in comparison to conventional dosage forms, such as customary tablets or capsules. Avoiding an undesirably high initial dose, the release is effected continuously over a relatively long period and controlled at an effective level. The retard form is administered orally and, once in contact with the stomach fluids, expands so as to float on the stomach fluids and/or be retained within the space of the stomach due to its size following inflation, which precludes passage across the pylorus sphincter. In this manner it remains in the stomach to insure continuous controlled release of the physiologically active ingredients.

A retard form is characterized preferably, at least in one form, by the following: (a) at least one component that expands on contact with bodily fluid (e.g., a substance that generates or constitutes a blowing agent), and/or a



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/566,458	01/30/2006	3739	725	P26,591-B USA	24	27	4

CONFIRMATION NO. 5084

23307  
 SYNNESTVEDT & LECHNER, LLP  
 2600 ARAMARK TOWER  
 1101 MARKET STREET  
 PHILADELPHIA, PA 191072950

ENTERED COMPUTER

## FILING RECEIPT



\*OC000000018933393\*

Date Mailed: 05/30/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

## Applicant(s)

Jagathesan Moodley, Athlone, IRELAND;

## Assignment For Published Patent Application

Merrion Research 1 Limited, Dublin, IRELAND

Power of Attorney: The patent practitioners associated with Customer Number 23307.

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/IB04/03414 07/30/2004  
 which claims benefit of 60/491,157 07/30/2003

## Foreign Applications

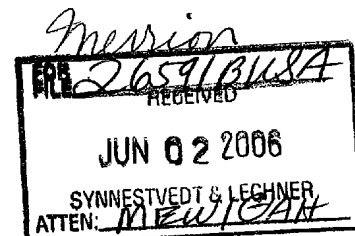
If Required, Foreign Filing License Granted: 05/24/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/566,458**

Projected Publication Date: 08/31/2006

Non-Publication Request: No

Early Publication Request: No



**\*\* SMALL ENTITY \*\*****Title**

Process and machine for automated manufacture of gastro-retentive capsules  
devices

**Preliminary Class**

600

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

---

### LICENSE FOR FOREIGN FILING UNDER

#### Title 35, United States Code, Section 184

#### Title 37, Code of Federal Regulations, 5.11 & 5.15

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).